The Remarks

Reconsideration and withdrawal of the rejections set forth in the Office Action dated November 29, 2005 are respectfully requested. Claims 29-33 are pending for examination.

I. Amendments

Claim 29 as amended relates to a method of preventing a relapse in a mammal with chronic, relapsing-remitting multiple sclerosis by orally administering interferon tau (IFNτ). Basis is found, for example, on page 17, lines 6-17 and in Example 3, beginning on page 30.

Claims 30 and 31 are amended to correct a minor clerical oversight.

Claim 34 is cancelled.

II. Double-Patenting Rejection

Claims 29-34 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 23-25, 28, and 31 of U.S. Patent No. 6,372,206 ("the '206 patent").

Claims 29-34 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 3, and 11 of U.S. Patent No. 5,906,816 ("the '816 patent").

These rejections are respectfully traversed for the following reason:

The issue of double patenting was addressed in *In re Vogel* (422 F.2d 438, 164 U.S.P.Q. 614 (Fed. Cir. 1970)), where, for obviousness-type double patenting, *Vogel* asks: "Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent?" The question seeks to determine if the invention of the pending application is a mere variation (which would have been obvious to those of ordinary skill in the art) of an already claimed invention.

The '206 patent recites claims to a method of "treating" an inflammatory disease condition in a mammal responsive to treatment by ovine or human interferon-tau comprising orally administering a therapeutically effective amount of interferon-tau through oral ingestion. The '816 patent recites claims to a method of "treating" multiple sclerosis in a subject in need of such treatment comprising administering to the subject a pharmaceutically effective amount of interferon-tau. In both patents, "treating" is defined as administering a substance effective to reduce the symptoms of the disease and/or lessen the severity of the disease (see col. 6, lines 37-

39 of the '206 patent; see col. 5, lines 9-11 of the '816 patent).

Applicants submit herewith a Declaration by Dr. Chih-Ping Liu to establish that "treating" a disease is distinguishable from "preventing a relapse in a mammal with chronic, relapsing-remitting multiple sclerosis." As noted in the Liu Declaration (¶7), the phrase "to reduce symptoms of the disease" refers to a reduction in the number of physical manifestations of the disease or to a reduction in the intensity of a particular physical manifestation, which for multiple sclerosis may include, for example, changes in sensation in the arms, legs, or face; vision problems; loss of muscle control; spasms; muscle weakness; numbness; etc. The intensity of these symptoms is a measure of the severity of the disease, so the phrase "lessen the severity of the disease" refers to a reduction in the intensity of the physical manifestations of the disease. (Liu Declaration ¶8). Disease severity can be assessed, for example, using a clinical scoring system, such as the system noted by Dr. Liu (¶8).

The claims in the '206 and '816 patents to "treating" refer to reducing the physical manifestations of the diseases and/or lessening the intensity of the physical manifestations, which are different from preventing a relapse of chronic, relapsing-remitting MS. A relapse in a mammal with chronic, relapsing-remitting multiple sclerosis is not considered by those of skill in the art to be a "symptom" of the disease (Liu Declaration ¶9).

Accordingly, the methods of the present invention are not an obvious variation of the methods claimed in the '206 and the '816 patents. Applicants hereby respectfully submit that the rejection of claims 29-33 be withdrawn for at least the reasons discussed above.

III. Rejections under 35 U.S.C. § 102

Claims 29-34 have been rejected under 35 U.S.C. §102(e) as allegedly anticipated by the '206 patent (U.S. Application No. 08/616,904) and the '816 patent (U.S. Application No. 08/406,190). Applicants respectfully traverse the rejection.

As stated on page 1 of the present application, "this application is a continuation of U.S. Application No. 10/029,890...; which is a continuation of U.S. Application No. 08/616,904...; which is a continuation-in-part of U.S. Application No. 08/406,190..." Accordingly, Applicants respectfully request withdrawal of the rejection on the basis that the present application is a continuation application based on the cited patents and, thus, cannot be anticipated by the cited

patents.

IV. Conclusion

In view of the foregoing, a Notice of Allowance is respectfully requested. If the examiner has any questions or believes a telephone conference would expedite prosecution of this application, the examiner is encouraged to call the undersigned at (650) 838-4388.

Respectfully submitted,
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